

Remarks

Non-elected claims 6, 7, and 12-37 have been canceled without prejudice, claims 1-5 have been amended, and claims 38 and 39 have been added. Claims 1-5, 8-11, 38, and 39 are pending. Support for the foregoing amendments may be found throughout the specification, for example at page 2, lines 20-23, page 5, lines 15-20, and in the original claims and the sequence listing. No new matter enters by these amendments. Table A and Table 2 have been reformatted in order to facilitate prosecution. No new matter enters by these amendments. Typographical errors have been corrected, such as, for example, by the addition of the letter "e" in the word PLACE after the Fac220 transcription factor in Table 2. *See* page 92, line 17 of the original specification. The "http://" and underlining have been removed from all website addresses on pages 39, 78, 79-81, 86, 87, and 94 of the specification. No new matter enters by these amendments.

I. Election/Restriction Requirement

Applicants acknowledge that Claims 6, 7, and 12-37 remain withdrawn from further consideration by the Examiner as allegedly being drawn to a non-elected invention. Applicants acknowledge the finality of the restriction requirement but maintain their traversal. The Office Action states that the restriction remains proper because "search and examination of more than one Group and/or sequence would be a serious burden...." Office Action at page 2. However, the Office has submitted no proof that a serious burden would be imposed by a search and examination of the entire application, including Claims 6, 7, and 12-37. Accordingly, for at least the foregoing reasons, Applicants maintain their traversal of the restriction requirement.

II. Information Disclosure Statement

Applicants thank the Examiner for the acknowledgement that the Information Disclosure Statement filed September 18, 2001 has been considered in full.

III. Specification

a. Objection to Tables 2 through 6

The Office objected to Applicants' disclosure because Table 2 on pages 91-93 of the specification was allegedly incomprehensible. Applicants respectfully disagree that "the columns ... are so scrambled that it is impossible to read the Tables." Office Action at page 3. Nonetheless, in order to facilitate prosecution, the formatting of Table 2 has been corrected as requested by the Office. The Office states that the objection to Table 2 will be overcome by this reformatting of Table 2. Accordingly, Applicants respectfully request that the objection to Table 2 be withdrawn.

Applicants note that although no objection was raised by the Office with respect to Table A on page 25 of the specification, in the interest of facilitating prosecution, Table A and the subsequent sentence on page 25 lines 8 through 20 have also been amended to correct formatting. No new matter enters by this amendment.

The Office objected to Tables 4-6 as allegedly being incomprehensible. Similarly, the Office objected to Table 3 as allegedly being "somewhat difficult to read." Office Action at pages 3-4. Applicants respectfully disagree with these objections. Tables 3-6, submitted on CD-ROM in a file labelled "pa_00329.txt", contain tab delimited text files and as such "maintain the spatial relationships (e.g., columns and rows) of the table elements and preserve the information they convey," thereby meeting the requirements of C.F.R. §1.58(b). When the file containing Tables 3-6 is opened using the Excel program, the columns appear perfectly aligned, the information is preserved, and the Tables are completely comprehensible in contravention to the Office's suggestion. Thus, it is respectfully suggested that the Office use the Excel program to open this file. From the Excel program, the Tables may also be printed if desired. Alternatively, the Tables may be opened in Wordpad, and the tabs set. From Wordpad, after setting the tabs, the Tables will appear aligned and may be readily printed.

b. Objection to embedded hyperlinks

The "http://" has been removed from all website addresses on pages 39, 78, 79-81, 86, 87, and 94 of the specification. The underlining has also been removed from all website addresses.

As such, the remaining website addresses do not contain embedded hyperlink or browser-executable code as specified in MPEP § 608.01 (d). According to MPEP § 608.01 (d), “examples of a hyperlink or browser-executable code are a URL placed between these symbols ‘<>’ and ‘http://’ followed by a URL address.” (MPEP Volume 7-1). Applicants’ disclosure, as amended, contains no such browser-executable code in the absence of embedded hyperlinks or browser-executable code. Accordingly, Applicants respectfully request that the Examiner withdraw the objection.

IV. Rejection Under 35 U.S.C. §101, Utility

Claims 1-5 and 8-11 were rejected under 35 U.S.C. § 101 for allegedly not being supported “by either specific, substantial and credible utility or, in the alternative, a well established utility.” Office Action at page 5. The Examiner acknowledges that Applicants have asserted utility for the nucleic acid molecules of the present invention, for example, as promoters or regulatory elements. *Id.* However, the Examiner contends that none of the utilities disclosed in the present application satisfy 35 U.S.C. § 101 because “[t]he examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.” *Id.*

Applicants respectfully point out that the “threshold for utility is not high: An invention is ‘useful’ under section 101 if it is capable of providing some identifiable benefit.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. See *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) (“when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown”).

Thus, the courts have expressed a test for utility that hinges on whether an invention provides an “identifiable benefit.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an “identifiable benefit” may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*,

51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

The present specification discloses multiple uses for the claimed nucleic acid molecules, including, as the Office has acknowledged, use as a regulatory region or promoter. *See, e.g.*, specification at page 1. Indeed, as the specification further provides, "the genetic enhancement of plants and seeds provides significant benefits to society," including, for example, the enhancement of plants and seeds "to have desirable agricultural, biosynthetic, commercial, chemical, insecticidal, industrial, nutritional, or pharmaceutical properties." *See, e.g.*, specification at page 2. Applicants respectfully submit that such uses provide both practical and substantial benefits. Such uses are neither incredible nor unbelievable. As such, Applicants respectfully submit that the present invention provides an identifiable benefit as defined by *Juicy Whip*.

The Office, however, argues that further research is necessary to determine whether SEQ ID NO: 1 is a regulatory element or promoter. Office Action at page 6. Applicants respectfully submit that the Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). Thus, the utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The law dictates that the Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

Moreover, the specification identifies multiple utilities for SEQ ID NO: 1, for example, as a marker in genetic mapping (*see e.g.*, Specification at page 54), to isolate promoters (*see e.g.*, Specification at page 58), to identify polymorphisms (*see e.g.*, Specification at page 58), and as a probe or primer (*see e.g.*, Specification at page 38).

Surprisingly, the Examiner also asserts that "SEQ ID NO: 1 appears to be free of the prior art, therefore there is not well-established utility for SEQ ID NO: 1." Office Action at page 6. However, the prior art does not dictate utility of a patentable invention, *i.e.*, the law imposes no requirement that in order to possess utility an invention must appear in the prior art. On the contrary, Applicants respectfully submit that utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). As described in the foregoing analysis, Applicants' specification discloses several specific, substantial and credible utilities for the claimed nucleic acid molecules.

Thus, based on the foregoing, Applicants respectfully submit that the utility rejection should be withdrawn. Any one of the disclosed utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. As such, reconsideration and withdrawal of this rejection are respectfully requested.

V. Rejection Under 35 U.S.C. §112, First Paragraph, Enablement

Claims 1-5 and 8-11 were rejected under 35 U.S.C. § 112, first paragraph, as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Office Action at page 7. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, the

enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement). Thus, based on the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, are respectfully requested.

Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned with respect to any unresolved issues remaining in this application.

Respectfully submitted,



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